Claim 12 (amended once): The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt.% of said composition based on the total weight of said implant composition.

REMARKS

Applicants wish to entertain the Examiner's offer to conduct a telephone interview prior to the examination of this response. Applicants had previously requested an interview, but the Examiner was unavailable at this time.

In view of the amendments and remarks that follow, Applicant respectfully submits that the application is in condition for allowance. Accordingly, Applicant requests reconsideration of the application, withdrawal of the objections, and rejections of record, and issuance of Notice of Allowance.

Claims 1-20 are pending in the application. Claims 1-20 stand rejected.

Applicants have amended Claims 1 to remove certain claim language and clarify the scope of anabolic agent to include the specific anabolic agents listed in page 6 of the specification. The derivatives of these anabolic agents discussed on page 6 of the specification are intended to be within the scope of amended claim 1. Applicants have also amended claim 11 and 12 to better define the meaning of weight % as suggested by the Examiner.

Rejections under 35 U.S.C. §102 (b) and 35 U.S.C. §103.

The Examiner rejected Claims 1-13, 16, 17 and 20 under 35 U.S.C. §102 (b) as being anticipated by Deasy (U.S. Pat. No. 4,874,612). Applicants respectfully traverse this rejection.

The Deasy formulation requires that each shaped piece of the multi-component implant contain biologically degradable copolymers of lactic acid and glycolic acid with a lactide to glycolide weight ratio of 90:10 to 60:40. See Column 1, lines 50-55 and Claim 1.

In contrast, the present invention is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each

formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Because the immediate-release first formulation consists essentially of an anabolic agent, it cannot contain biologically degradable copolymers of lactic acid and glycolic acid with a lactide to glycolide weight ratio of 90:10 to 60:40. A significant difference between the controlled release formulation and the immediate release formulation of the present invention is that the controlled-release formulation has a polymer matrix, such as poly(D,L-Lactide-co-glycolide) to control the release of the anabolic agent, and the immediate-release formulation does not have a polymer matrix to control the release of the anabolic agent. (See page 7 of specification). To include the biologically degradable copolymers of lactic acid and glycolic acid with a lactide to glycolide weight ratio of 90:10 to 60:40 in the immediate release formulation of the present invention, as Deasy would require, would change the essential characteristics of the immediate release formulation. Furthermore, Deasy does not disclose or suggest using an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Accordingly, the present invention is not anticipated by the Deasy reference.

The terms "first" and "second" "are terms well known in the art and are commonly used in claim language to distinguish elements in a claim. For instance, U.S. Patent No. 6.117,433 to Edens et al. discloses in claim 1 a dual chamber disbursing system comprising "first" and "second" aqueous compositions in claim 1. In another example, U.S. Patent No. 6,322,773, discloses in claim 1 a dual compartment squeeze tube which includes a "first" formulation and a "second" formulation.

The terms 'controlled' (or sustained) and 'immediate' are also terms well known in the art. In the present application, controlled release (or sustained release) and immediate-release formulations are defined on page 7 of the specification. As stated above, a significant difference between the controlled release formulation and the immediate release formulation of the present invention is that the controlled-release formulation has a polymer matrix, such as poly(D,L-Lactide-co-glycolide) to control the release of the anabolic agent, and the immediate-release formulation does not have a polymer matrix to control the release of the anabolic agent. Similarly, U.S. Serial No 09/912774 in claim 26 discloses a dual release formulation which includes a "controlled release composition" in combination with an "immediate release composition." In another example, U.S. Patent No. 5,500,227 discloses

in claim 1 a sustained release tablet comprising an immediate release tablet core and a film coating the core comprising a sufficient amount of hydrophobic material to provide a sustained release.

In regard to the term "weight %" in claims 11 and 12 of the present application, applicants have amended claims 11 and 12 to replace the phrase "total weight percentage basis" with the phase "total weight of said implant composition" as phrased in claim 19.

A rejection under 35 U.S.C. §102 (b) requires that each and every element of a rejected claim be disclosed by the prior art relied upon by the Examiner for making this rejection. Since Deasy does not disclose or suggest a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof, accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 1-5, and 7-13 under 35 U.S.C. 102(b) as being anticipated by Ivy, (U.S. Pat. No. 4,670,249). Applicants respectfully traverse.

The Ivy formulation is a mixture of a growth-promoting hormone *and* a zearalin. See Col. 1, lines 19-21. The present invention differs from Ivy, because the present invention is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Ivy requires using only growth hormone and zearalin. Ivy does not disclose or suggest using an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, or combinations thereof. Accordingly, Applicants, therefore, respectfully request withdrawal of this 102(b) rejection.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Deasy, in view of Ivy, O'Callaghan, Sivaramakrishnan and Kim. As explained above, the present invention is not suggested or disclosed in Deasy or Ivy. None of the additional references disclose or suggest a dual formulation composition comprising an immediate-

release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, or combinations thereof. Applicants, therefore, respectfully request withdrawal of this rejection under 35 U.S.C. §103(a).

The Examiner rejected Claims 1-8, 13, 14, 16, 18-20 under 35 U.S.C. §102 (b) as being anticipated by or in the alternative under 35 U.S.C. §103(a) as being obvious over Gresser (WO. 93117704). Applicants respectfully traverse this rejection.

Gresser discloses biodegradable polymeric multiphasic release system of one or more bursting units wherein each bursting unit each bursting unit includes a bioactive agent encapsulated in a biodegradable, biocompatible polymeric membrane. See Page 4, lines 23-26.

In contrast, the present invention is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Because the immediate-release first formulation consists essentially of an anabolic agent, it cannot contain a biodegradable, biocompatible polymeric membrane. As stated above, a significant difference between the controlled release formulation and the immediate release formulation of the present invention is that the controlled-release formulation has a polymer matrix, such as poly(D,L-Lactide-co-glycolide) to control the release of the anabolic agent, and the immediate-release formulation does not have a polymer matrix to control the release of the anabolic agent. (See page 7 of specification). To include the biodegradable, biocompatible polymeric membrane. in the immediate release formulation of the present invention, as Gresser would require, would change the essential characteristics immediate release formulation. Furthermore, Gresser does not disclose or suggest using an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Accordingly, the present invention is not anticipated by the Gresser reference.

The Examiner rejected Claims 1-13, 16, 17, 19, and 20 under 35 U.S.C. §102 (b) as being anticipated by Lewis (U.S. Patent No. 5,288,496). Applicants respectfully traverse this rejection.

Lewis discloses biodegradable coating formulations for coating sustained-release drug implants, wherein the formulation comprises a water soluble pore-forming agent mixed with water insoluble polymers. See Column 6, lines 25-32.

In contrast, the present invention is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Because the immediate-release first formulation consists essentially of an anabolic agent, it cannot contain a water soluble pore-forming agent mixed with water insoluble polymers. As stated above, a significant difference between the controlled release formulation and the immediate release formulation of the present invention is that the controlled-release formulation has a polymer matrix, such as poly(D,L-Lactide-co-glycolide) to control the release of the anabolic agent, and the immediate-release formulation does not have a polymer matrix to control the release of the anabolic agent. (See page 7 of specification). To include the water soluble pore-forming agent mixed with water insoluble polymers in the immediate-release formulation of the present invention, as Lewis would require, would change the essential characteristics of the immediate release formulation. Furthermore, Lewis does not disclose or suggest using an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Accordingly, the present invention is not anticipated by the Lewis reference.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Lewis, in view of Lee. As explained above, the present invention is not suggested or disclosed in Lewis. Lee does not disclose or suggest a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone,

salbutamol, progesterone, trenbolone acetate, and combinations thereof. Applicants, therefore, respectfully request withdrawal of this rejection under 35 U.S.C. §103(a).

None of the references cited by the Examiner, alone or in combination, disclose or suggest the present invention. Applicants, therefore, believe that whether used alone or in combination, the references cited by the Examiner do not anticipate or render the present invention obvious.

There being no other rejection pending, Applicants believe that Claims 1-20 are in condition for allowance, and such action is earnestly requested. If the Examiner has any questions, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on

June 18, 2002

Robert L. Bernstein
Registered Representative

Robert L. Bernstein 6/18/02
Signature and Date of Signature

Marked Up Version of Amended Claims
(Added terms are underlined and deleted terms are in brackets)

Claim 1 (twice amended): An anabolic implant dual formulation composition [for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition] comprising: (i) an immediate-release first formulation comprising consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation, and wherein said anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof.

Claim 11 (amended once): The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 50 wt.% to about 95 wt.% of said composition based on [a] the total weight [percentage basis] of said implant composition.

Claim 12 (amended once): The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt.% of said composition based on the total weight of said implant composition.